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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/752,939	12/29/2000	Bruce L. Gibbins	01307.0003U2	9231
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

09/752,939

Applicant(s)

GIBBINS ET AL.

Examiner

Isis A. Ghali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,6,8,21,23-28,31-35,38-43,45-59 and 61-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6,8,21,23-28,31-35,38-43,45-59 and 61-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of Interventions Filed (PTO-502)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The receipt is acknowledged of applicants' request for RCE and copy of the declaration previously submitted on 02/14/2007, both filed 01/18/2011.

Claims 1, 2, 4, 6, 8, 21, 23-28, 31-35, 38-43, 45-59, 61-72 are pending and included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/18/2011 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 2, 4, 6, 8, 21, 23-28, 31-35, 38-43, 45-59, 61-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ladin (US 5,792,090, of record) in view of Gibbins (US 5,928,174, currently listed on PTO 892) and Murdock (US 2002/0042587, of record).

Applicant's claims

Claim 1 as currently presented is directed to an oxygen-delivery wound treatment, comprising a biocompatible, single unit matrix for delivering oxygen, comprising a) a swellable, cross-linked polyacrylamide polymer network, b) deliverable oxygen in elastic closed cells that are permeable to gas within the cross-linked polyacrylamide polymer network wherein after the polyacrylamide polymer network is cross-linked, the closed cell are formed by oxygen produced by reacting the catalyst and a second reactant, and wherein with use of the matrix, oxygen is delivered from the closed cells.

Claim 38 as currently presented is directed to an oxygen delivery wound treatment device, comprising a biocompatible, single unit matrix for delivering oxygen, comprising; a) a swellable, cross-linked polyacrylamide polymer network, b) deliverable oxygen in elastic closed cells that are permeable to gas and within the cross-linked polyacrylamide polymer network a second reactant and a catalyst reaction occurred, and c) at least one active agent.

Claim 39 as currently presented is directed to a biocompatible, single unit cross-linked polyacrylamide matrix, comprising a swellable, cross-linked polyacrylamide polymer network, and derivable oxygen in elastic closed cells that are permeable to gas and within the cross-linked polyacrylamide polymer network at sites where a reaction of a catalyst and a second reactant occurred.

The present claims 1, 38 and 39 recite a product comprises matrix of closed cell foam of cross-linked polyacrylamide polymer containing oxygen produced by reaction of catalyst and reactant. The limitation of oxygen delivery is directed to intended use that

impart patentability to composition claims. The limitation when oxygen is produced in the crosslinked polyacrylamide network is directed to process of making the product. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695,698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Determining the scope and contents of the prior art (MPEP § 2141.01)

Ladin teaches wound dressing that supply oxygen to the wound for optimal healing and minimization of infection because the wound causes diffusion limited access and limits the oxygen supply to the wound (abstract; col.2, lines 28-31). The dressing comprises polymeric foam comprising elements that react to generate oxygen that are hydrogen peroxide and catalyst such as magnesium dioxide or enzymes (col.6, lines 6-26). The catalyst is contained in the foam which absorbs hydrogen peroxide into the foam to produce oxygen (col.7, lines 48-55). The foam comprises guar gum or polyacrylamide, and further comprises collagen, i.e. non-gellable foam (col.4, lines 39-42; col.12, line 7).

**Ascertaining the differences between the prior art and the claims at issue,
and resolving the level of ordinary skill in the pertinent art (MPEP § 2141.012)**

Although Ladin teaches polyacrylamide foam, however, the reference does not explicitly teach crosslinked polyacrylamide or closed cell foam in particular.

Gibbins teaches wound dressing comprising cross-linked polyacrylamide polymer matrix that is flexible and elastic, permeable to substances such as aqueous fluids and dissolved gaseous agents including oxygen. (See col.4, lines 62-67; col.5, lines 12-17).

Murdock teaches polymeric cross-linked foam reservoir comprising cellulose derivatives and active agent including anti-infective agents and growth factors (abstract; paragraphs 0035, 0049, 0050). The foam reservoir is closed cell foam wherein the closed cells can be produced chemically and contains gasses including oxygen (paragraph 0036). The closed cell foam provides thin matrix with high surface area with respect to the matrix (paragraphs 0011, 0016).

Resolving the level of ordinary skill in the pertinent art (MPEP § 2141.012)

Therefore, at the time of the invention it was known to treat wound using polyacrylamide foam matrix containing oxygen produced by chemical reaction between peroxide and catalyst as taught by Ladin, and replace polyacrylamide by crosslinked polyacrylamide taught by Gibbins. One would have been motivated to do so because Gibbins teaches that cross-linked polyacrylamide polymer matrix that is flexible and elastic, permeable to substances such as aqueous fluids and dissolved gaseous agents including oxygen. One would reasonably expected formulating elastic flexible crosslinked polyacrylamide foam matrix containing oxygen that is produced chemically

by the reaction of peroxide and catalyst wherein the foam is optimal for wound healing and can accommodate the oxygen released by the reaction of peroxide and catalyst.

Further, it would have been obvious to one having ordinary skill in the art at the art at the time of the invention to use the closed cell foam taught by Murdock in the foam matrix taught by the combination of Ladin and Gibbins because Murdock teaches that closed cell crosslinked polymer foam matrix is thin and has high surface area with respect to the matrix and oxygen can be delivered chemically in foam. One would reasonably expect formulating elastic flexible crosslinked polyacrylamide closed cell foam matrix containing oxygen that is produced by the reaction of peroxide and catalyst wherein the matrix is thin, yet can accommodate oxygen and therapeutic agents.

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a) because the invention as a whole is taught by the combined teaching of the cited references.

Response to Arguments

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6. Applicant's arguments filed 01/18/2011 have been fully considered but they are not persuasive.

Applicants argue that Murdock teaches polymeric foam reservoirs for an electrotransport delivery device, and does not teach wound treatment. The polymeric reservoir of Murdock incorporates gases into a polymeric matrix to act as inert filler, increasing the surface area of the matrix without introducing the drawbacks of comment 'inert' fillers, such as glass beads, etc. No gas is released from the bubbles in the Murdock reservoir. If the gases were to be released, purpose of the Murdock polymeric reservoir would be destroyed.

In response to this argument, applicants' attention's directed to the scope of the present claims, that is directed to product, and all the elements of the claims are taught by the combined teachings of the prior art. Murdock is relied upon for teaching the closed cell type of foam to be known at the time of the invention. The intended use of the device does not impart patentability to the claims. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Regarding the argument of gas bubbles of Murdock are used as inert material, it is argued that gas bubbles of Murdock deliver active agents and its combination with Ladin teaches delivery of oxygen to the application site. One cannot attack the references individually wherein the obviousness is based on combination of the

references. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Applicants argue that they met their burden and have shown that closed cell crosslinked polyacrylamide foam containing oxygen in the cells, made by the method of Murdock and containing oxygen as taught by Ladin, "does not deliver oxygen under the same environmental circumstances" when compared the Applicants' currently claimed invention. Applicants have submitted Gibbins Declaration, February 14, 2007, with data that shows that the Murdock device, does not release oxygen, see Figures 1 and 2, whereas Applicants' currently claimed device releases an increasing amount of oxygen "under the same environmental circumstances". The total mount of deliverable oxygen in the Murdock device after 24 hours was 0.1 ppm oxygen, whereas "under the same environmental circumstances", Applicants' currently claimed device released approximately 2.8 ppm oxygen.

In response to this argument, it is argued that, it is argued that the present invention as a whole as currently claimed is taught by combination of Ladin, Gibbins and Murdock. Gibbins teaches elastic crosslinked polyacrylamide that capable to deliver oxygen. The declaration was done based on combination of Murdock and Ladin. The present invention as a whole is taught by the combination of Ladin, Gibbins and Murdock, and would have been prima facie obviousness in the meaning of USC 103 (a).

Applicants argue that the prior art structure is not capable of performing the intended use, as evidenced by the teachings of the prior art and the experiments conducted by Applicants. The prior art does not "meet the claim". Applicants currently pending claims recite a structural difference between the claimed invention and the prior art- the currently claimed invention delivers oxygen from elastic closed cells that are permeable to gas.

In response to this argument, it is argued that all the elements of the present current claims are taught by the combination of the prior art, and would expect to have the same properties and exhibits the same functions, or applicants' invention is incomplete. Gibbins teaches elastic crosslinked polyacrylamide that is capable to deliver oxygen. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

Regarding applicants argument concerning Marans patent, it is moot in view of the new ground of rejection.

Applicants argue that foaming is not taught in Ladin.

In response to this argument, it is argued that production of gas is foaming and is taught by Ladin as it teaches using the claimed catalyst and reactant. Ladin teaches

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production of oxygen into polymer, i.e. foaming. The three references relied upon in the current rejection in combination teach the present invention as a whole. The combination of the references teaches closed cell foam of crosslinked polyacrylamide containing oxygen in the closed cells, which is the product currently claimed. It is expected that when the product taught by the combination of the prior art is exposed to the same environment, such as wound, the product will behave the same way and react with the environment and release active agents and/or oxygen since materials and their properties are inseparable.

Applicants argue that the currently claimed invention is a product that delivers oxygen from elastic closed cells that are permeable to oxygen. Applicants have disclosed an invention that has superior and unexpected results, a device that delivers oxygen, when compared to prior art combination that does not deliver oxygen or gas.

In response to this argument, it is argued that the Gibbins clearly teaches crosslinked polyacrylamide that is elastic and flexible and permeable to oxygen. Combination of the cited references would teach the present invention as a whole.

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter as a whole as defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a) because the invention as a whole is taught by the combined teaching of the cited references.

Response to Amendment

7. The declaration under 37 CFR 1.132 filed 02/14/2007 is insufficient to overcome the rejection of claims 1, 2, 4, 6, 8, 21, 23-28, 31-35, 38-43, 45-59, 61-72 based upon U.S.C. 103(a) over the combination of Murdock, Marans and Ladin as set forth in the last Office action. The declaration is moot in view of the new ground of rejection. In any event, the declaration failed to overcome the rejection because: it include(s) statements which amount to an affirmation that the claimed subject matter functions as it was intended to function. This is not relevant to the issue of nonobviousness of the claimed subject matter and provides no objective evidence thereof because the prior art in combination would deliver the present invention as a whole. Further, there is no showing that others of ordinary skill in the art were working on the problem and if so, for how long. In addition, there is no evidence that if persons skilled in the art who were presumably working on the problem knew of the teachings of the above cited references, they would still be unable to solve the problem.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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